K090427

IV. 510K SUMMARY

JAN 29 2010

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of SMDA 1990 and 21CFR 807.92.

Submitter:	Curative Medical Technology Inc . 198 Xiangjiang Road New District, Suzhou 215011 P. R. China
Company Contact Person:	Ms. Jessica Chiu, General Manager
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Date of Summary:	September 25, 2009
Device Name:	Ursa™ Angiographic Catheter
Device Classification Name:	Diagnostic Intravascular Catheter (74DQO) 21 CFR 870.1200
Predicate Device:	Infiniti Angiographic Catheter manufactured by Cordis, K970854 (September 30, 1997). Jography Angiographic Catheter manufactured by Abbott, K000825 (September 21, 2000)

Device Description:

The Ursa™ angiographic catheters are sterile, single use, disposable devices designed to deliver radiopaque contrast media to selected sites in the vascular system. It is available in 39 different curve shapes and three sizes of 4, 5 and 6F. Each device consists of a catheter with luer connector; strain relief, catheter shaft, catheter soft extension and soft distal tip. The distal end of the catheter is formed into a variety of shapes required to access a variety of vascular anatomies. All versions of the catheters are designed to accept a maximum guidewire diameter of 0.038" and have a strain relief at the hub to shaft junction. Sideholes may be incorporated into the shaft to facilitate injection of radiopaque contrast media.

Intended Use:

The Ursa™ angiographic catheter is intended for use in the delivery of radiopaque contrast media to selected sites in the coronary and peripheral vasculature. The device is for single use only. This device is not intended for use in the neurovasculature.

Summary of Technological Characteristics in Comparison to Predicate Device:

The Ursa™ Angiographic Catheter has the same intended use and employs a similar method of operation and design as compared to the predicate devices. Both the new and predicate devices consist of a proximal connector, shaft, and distal tip. Both the new and predicate devices are comprised of similar materials and serve as passive conduits for the delivery of contrast media under high pressure.

Performance Data:

Performance testing was conducted on the Ursa™ Angiographic Catheter to establish substantial equivalence. Testing was conducted according to protocols based on international standards and in-house requirements and included dimensional and functional testing. Additionally, the catheters were subjected to biocompatibility testing per ISO 10993.

Conclusion:

The information and data provided in this 510(k) Notification establish that the Ursa™ Angiographic Catheter is substantially equivalent to the legally marketed predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

Curative MedicaL Technology, Inc.
c/o Ms. Amy E. McKinney, MS, RAC
Regulatory Affairs Consultant
102 Mistletoe Street
Lake Jackson, TX 77566

JAN 29 2010

Re: K090427
Trade/Device Name: Ursa™ Angiographic Catheter
Regulation Number: 21 CFR 870.1200
Regulation Name: Diagnostic Intravascular Catheter
Regulatory Class: Class II (two)
Product Code: DQO
Dated: January 15, 2010
Received: January 19, 2010

Dear Ms. McKinney:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K090427

Device Name: Ursa™ Angiographic Catheter

Indications For Use:

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This device is not intended for use in the neurovasculature.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K090427